December 18th, 2025

Natec Medical Ltd.
Pallippatt Roy Devassy
Head of Clinical & Regulatory Affairs
Ava Technoparl, MedTech Road, Cote D'Or Technopole,
Minissy, Cote D'Or
Moka, 80829
Mauritius

Re: K251915
Trade/Device Name: Amethyst HP PTA OTW 0.035" Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT
Dated: November 17, 2025
Received: November 17, 2025

Dear Pallippatt Roy Devassy:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shelby Buffington -S

Digitally signed by Shelby Buffington -S
Date: 2025.12.18 16:57:51 -05'00'

For Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251915

Device Name
Amethyst HP PTA OTW 0.035" Catheter

Indications for Use *(Describe)*
The Amethyst HP PTA OTW 0.035" Catheter is indicated for:
- Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature including iliac, femoral, popliteal, tibial, peroneal, subclavian, renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
- Post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807.92.

Applicant: Natec Medical Ltd.
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Preparation Date: Dec 17, 2025

Device Name:

Trade Name:	Amethyst HP PTA OTW 0.035” Catheter
Common/Regulatory name:	Percutaneous catheter
Classification Name:	Percutaneous transluminal angioplasty catheter
Generic name:	PTA Catheter
Regulation Number:	21 CFR 870.1250
Product Code:	LIT
Device Class:	Class II

Predicate Devices: Amethyst HP PTA OTW 0.035” Catheter – K241040

Device Description:

The Amethyst HP PTA OTW 0.035” catheter is a balloon catheter consisting of an over the wire catheter with a non-compliant inflatable balloon fixed at the distal end of the tip. The balloons are designed to provide consistent balloon diameters and lengths at high pressures. A tapered tip

positioned at distal of the balloon facilitates the advancement of the catheter to and through the stenosis. A Luer lock fitting (Y hub) at the proximal end allows connection with an inflation device. The catheter is a co-axial catheter with a balloon at the distal tip. One lumen is used for the inflation of the balloon and is accessed via the lateral port of the Y hub. The second lumen, start at the straight entry port of the Y hub, allows access to the distal tip of the catheter for guide wire insertion. The balloon has two radiopaque markers to aid in positioning the balloon relative to stenosis. The balloon is dilated using the lateral port, at which the balloon opens to a known diameter at a specific pressure. The maximum recommended guide wire diameter is 0.035". The catheter is supplied sterile and is intended for single use.

The Amethyst HP PTA OTW 0.035" catheter is available in following sizes;

Table 1: Balloon Size Matrix

Catheter Usable lengths 50, 75 & 135 cm						
Balloon Size		Balloon Length (mm)				
		20	40	60	80	100
Balloon Diameter (mm)	4.00	✓	✓	✓	✓	✓
	5.00	✓	✓	✓	✓	✓
	6.00	✓	✓	✓	✓	✓
	7.00	✓	✓	✓	✓	✓
	8.00	✓	✓	✓	✓	✓
	9.00	✓	✓	✓	✓	
	10.00	✓	✓	✓	✓	
	12.00	✓	✓			

Device Indication for Use:

The Amethyst HP PTA OTW 0.035" Catheter is indicated for:

- Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature including iliac, femoral, popliteal, tibial, peroneal, subclavian, renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
- Post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

Comparison of Technical Characteristics:

The design, materials and manufacturing of the Amethyst HP PTA OTW 0.035" Catheter is same or similar to those used for the predicate devices. The intended use for the Amethyst HP PTA OTW 0.035" Catheter is also comparable to the predicate devices.

Details	Subject Device (Amethyst HP PTA OTW 0.035" Catheter)	Predicate devices (Amethyst HP PTA OTW 0.035" Catheter - K241040)
Catheter usable length	50, 75 & 135 cm	50, 75 & 135 cm
No. of Radiopaque Ring Markers in the balloon	2	2
Balloon type	non-compliant	non-compliant
Balloon Diameters	4.00 to 12.00mm (Addition of balloon diameter i.e. 4, 5, 6 & 12mm and soft material change on all diameter)	7.00 to 10.00mm
Balloon lengths	20 to 100mm	20 to 100mm
Soft tip Materials	Soft material changed to Pebax (non-radiopaque) (All other device materials remain identical to those used in the predicate device (K241040)).	Radiopaque soft tip
Rated Burst Pressure (RBP)	30, 35 & 40 ATM	35 & 40 ATM
Nominal Pressure (NP)	8 ATM	8 ATM
Guide wire compatibility	0.035"	0.035"
Introducer sheath compatibility	6, 7 & 8F	6 & 7F
Packaging	Tyvek pouch packaging	Tyvek pouch packaging
Sterilization method	Ethylene oxide	Ethylene oxide
Single use device	Yes	Yes

Biocompatibility:

Biocompatibility testing previously conducted on the predicate device is leveraged to support the subject device. The predicate device was evaluated in accordance with ISO 10993-1: Biological Evaluation of Medical Devices – Evaluation and Testing, and all testing was performed in compliance with 21 CFR Part 58 (Good Laboratory Practice). The test results demonstrated that the materials are biocompatible for the intended intravascular use.

The following biocompatibility tests were completed on the Amethyst HP PTA OTW 0.035"

Catheter.

- Acute Systemic Toxicity Study
- Cytotoxicity Study
- Hemolysis Test
- Sc5b-9 Complement Activation
- Intracutaneous Reactivity Test
- Material Mediated Pyrogen Test
- Skin Sensitization Study
- Thromboresistance evaluation test
- Partial Thromboplastin Time (PTT) Assay test
- Heparinized Blood Platelet and Leukocyte Count Assay

Performance Data:
Substantial equivalence has been demonstrated based on the results of non-clinical testing on the Amethyst HP PTA OTW 0.035" Catheter which addressed the following considerations:

- Dimensional Verification
- Balloon Fatigue test (Repeat Balloon Inflations)
- Catheter Torque Strength evaluation
- Balloon Fatigue in stent (Repeat Balloon Inflations)
- Balloon Inflation and Deflation Time
- Balloon Rated Burst Pressure (RBP) and compliance test
- Balloon Rated Burst Pressure (RBP in Stent)
- Catheter Bond (balloon sleeve and hub) tensile strength
- Catheter soft tip bond tensile strength
- Re-wrapping tool compatibility test
- Balloon Preparation, Deployment and Retraction
- PTA Catheter Performance test (trackability and retraction force)
- Flexibility and kink test

Radiopacity test for the Amethyst HP PTA OTW 0.035" Catheter is leveraged from the legally marketed predicate device (K241040) as there is no change in radiopaque marker used on the product.

Packaging validation for the Amethyst HP PTA OTW 0.035" Catheter is leveraged from the legally marketed predicate device (K241040). The packaging materials, configuration, and sterilization process remain unchanged from the predicate device; therefore, the previously completed packaging integrity and performance validation testing is applicable to the subject device.

- Package integrity testing
  - Simulated shipping and climatic conditioning (shipping) study
  - Packaging box and label visual inspection

- Seal & Peelable pouch Visual Inspection
- Seal width (Dimensional) Verification
- Seal tensile strength
- Peeled pouch Seal Visual Inspection
- Seal Dye Penetration
- Bubble leak test
- Product Sterility test

Conclusion:

The subject device, the Amethyst HP PTA OTW 0.035" Catheter met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, FDA guidance documents and test protocols.

Based on the similarities in the indication for use, device design, materials and the results of the non-clinical testing and analysis, the Amethyst HP PTA OTW 0.035" Catheter is considered substantially equivalent to the predicate device.